EFFECT OF YOGA THERAPY IN MODIFYING STRESS IN PATIENTS WITH PSORIASIS: A RANDOMIZED CONTROL TRIAL

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1. Introduction

1.1 Background:

Psoriasis is a common, chronic, immune-mediated inflammatory skin disease. The disease affects 3.0%–4.9% of the Asian population and is associated with metabolic, cardiovascular, and psychiatric comorbidities that influence patients' quality of life (QoL). Psoriasis is a chronic skin disease characterized by sharply demarcated erythematous plaques covered by silvery-white scales. Psoriatic lesions involve hyperproliferation and aberrant differentiation of epidermal keratinocytes and infiltration of activated CD4+ Th1 and Th17 lymphocytes into the dermis. Recent advances in basic research (biomedical progresses) and the translation of this information into clinical practice (therapeutic innovations) have improved the understanding of psoriasis. Importantly, after the introduction of several effective biologics targeting the interleukin (IL)-23/IL-17 axis, psoriatic patients can achieve almost complete skin clearance. Despite the excellent safety and efficacy profiles of these biologics, unmet needs remain for a substantial number of patients due to the lack of efficacy, unfavorable safety, costs, and inconvenience. Therefore, it is important to identify novel pathogenic mechanisms and unmet clinical needs to facilitate basic and clinical research on psoriasis.

1.2. Definition and Epidemiology

Psoriasis represents one of the most common skin diseases affecting up to 14% of world populations, depending on the specific cohort and scrutinized criteria.(1) It is a chronic disease entailing lamellar lesions, lockout of hair follicles resulting in hair loss, and inhibition of sweat and sebaceous glands, resulting in dry skin. In humans, psoriasis affects mostly the regions above the neck, which have the maximum concentration of skin appendages. However, it can also invade genital regions and fingernails. Disease exacerbation is temperature, moisture, and stress-dependent. A brief clinical description of psoriasis, from molecular mechanisms to the macroscopical presentation, can be found in other reviews.

Psoriasis affects 2-3% of the population in Western countries and about 1% in East Asian countries, and its prevalence in rural populations is considerably lower than in urban ones. The sex ratio of psoriasis is 1:1, but mild forms, less than 10% of the body surface area, predominantly affect men, while severe forms, above 10% of body

surface area, predominantly affect women, which correlates with differences in education and social movements of men and women.(2,3) There is still no successful disease-preventive medication, and the presence of lesions significantly impairs the physical and mental health of patients. As in any chronic disease, psoriasis has both physical and psychosocial components.

1.3 Pathophysiology:

Psoriasis is a chronic, immune-mediated skin disease characterized by a scaly rash. It affects 1-3% of the population and is associated with comorbidities such as psoriatic arthritis, cardiovascular disease, and depression. The underlying mechanisms of psoriasis are still being investigated, but genetic predisposition leading to systemic inflammation is now accepted as a relevant paradigm to explain the development and propagation of the disease.(4) Initially thought to be a benign disease that affected just the skin, psoriasis is now recognized as a systemic illness. The development and persistence of psoriatic lesions is not only because of a dysfunction in the immune system but also due to ecological changes that alter the innate and adaptive response of the PSC. These aberrations are sustained by genetic mutations and polymorphisms that may render an individual susceptible to psoriasis. There is also emerging evidence that stress, including both psychosocial events and severe lipotoxicity, promotes the onset of the disease. Nevertheless, the most important alleles associated with familial psoriasis risk were found in immune system-related genes.

1.4 The Role of Stress in Psoriasis:

Psoriasis, a chronic inflammatory skin disease, is known to have exacerbation episodes, often linked with stressful life events. A workshop of leading experts convened by the International Psoriasis Council aimed to investigate the current understanding of how stress and other psychological factors affect persons with psoriasis. Changes to the skin induced by temporal psychological active circuits seem to underlie the effect of stress on psoriasis. Importantly, psoriasis must be made more susceptible to the influence of stress not only due to changes in external elements, such as increased release of stress hormones, increased accessibility of IL-1 released by external stressors, and changes in neurotransmission, to activate the skin innate immune system but also in its genetic background.(1)

Currently, the focus has been directed to the skin-act in the interaction of the brain with its environmental milieu with involvement of hormones and neurotransmitters. In the skin, neuropeptides may directly affect cells of the immune system and skin metabolism. The communication axis of the skin and the CNS is reciprocal since signals from the skin also impact the functioning of the brain.(5) Neuropeptides released from the skin have been found in CNS structures. Such neuropeptides are substance P and calcitonin gene-related peptide, suggesting that these are pathways through which the skin viscerally communicates with the brain.

1.5 Yoga as an adjuvant therapy:

The potential of yoga as an adjuvant therapy extends beyond stress reduction. A systematic review by Cramer et al. found evidence for the efficacy of yoga in improving pain and functional disability in chronic low back pain patients.(8) Another review by Pascoe et al. suggested that yoga might be beneficial as an adjunct treatment for depression.(9)

In the context of autoimmune disorders, a study by Evans et al. found that yoga improved fatigue and mood in patients with multiple sclerosis.(10) These findings highlight the potential of yoga to address multiple aspects of chronic conditions, including both physical and psychological symptoms.

1.6 Yoga and stress reduction

The stress-reducing effects of yoga have been extensively studied, with research exploring both psychological and physiological outcomes. A systematic review by Pascoe and Bauer found that yoga interventions were associated with reduced evening cortisol, waking cortisol, ambulatory systolic blood pressure, resting heart rate, high frequency heart rate variability, fasting blood glucose, cholesterol, and low density lipoprotein.(9) These findings suggest that yoga can modulate both the HPA axis and the sympathetic nervous system.

Neuroimaging studies have also provided insights into the mechanisms underlying yoga's stress-reducing effects. A study by Villemure et al. found that experienced yoga practitioners had greater gray matter volume in brain regions involved in stress regulation, including the hippocampus and anterior cingulate cortex.(11)

Moreover, recent research has explored the molecular mechanisms of yoga's effects. A study by Tolahunase et al. found that a yoga and meditation intervention was

associated with changes in gene expression related to oxidative stress, DNA damage, cell cycle regulation, and inflammation.(12)

1.7 Yoga and psoriasis:

While research specifically on yoga and psoriasis remains limited, studies on related conditions provide valuable insights. A randomized controlled trial by Ganesan et al. found that yoga significantly improved quality of life and reduced disease activity in patients with rheumatoid arthritis, another immune-mediated inflammatory disorder.(13)

In the context of skin conditions, a study by Garubard et al. suggests that mind-body therapies may be considered in the treatment as adjunct therapy for several dermatologic conditions, including atopic dermatitis, psoriasis, self-induced skin conditions, and others.(14)

1.8 Stress reduction and psoriasis outcomes:

Building on the work of Kabat-Zinn et al., recent studies have further explored the impact of stress reduction on psoriasis outcomes. A randomized controlled trial by Fordham et al. found that cognitive-behavioral therapy combined with standard treatment improved clinical outcomes and quality of life in psoriasis patients compared to standard treatment alone.(15)

Additionally, a study by Piaserico et al. demonstrated that a short-term stress management program improved psoriasis severity and quality of life, with effects persisting at 6-month follow-up.(16) These findings underscore the potential of integrating stress reduction techniques into psoriasis management.

This deeper analysis further emphasizes the potential value of our research question. It highlights the complex interplay between stress and psoriasis, the multifaceted effects of yoga on both physiological and psychological parameters, and the need for comprehensive assessment in psoriasis research. Our proposed study could contribute significantly to our understanding of yoga as an adjuvant therapy for psoriasis, potentially addressing both stress reduction and clinical outcomes.

2. Aim and Objectives:

2.1 Aim:

To study the effect of yoga as adjuvant therapy in modifying stress in patients with Psoriasis.

2.2 Objectives:

2.2.1. To evaluate the effect of adjuvant yoga practices in modifying stress in patients with psoriasis on

- Anthropometric parameters (Weight (Wt), Body Mass Index (BMI)).
- Physiological parameters (Blood Pressure (BP), Heart rate (HR)).
- Psychological parameters (Perceived Stress Scale (PSS), Dermatology Life Quality Index (DLQI)).
- Biochemistry parameter (Salivary cortisol).

2.2.2. To evaluate clinical changes through Psoriasis Area and Severity Index (PASI) scale.

3. Research Question

Does adjuvant yoga therapy modify stress and improve the clinical parameters in patients with Psoriasis?

4. Brief Review of Literature

Yoga helps unify all aspects of our being: the physical body, in which we live our daily life; the energy body, which gives us the capacity to do what we do; the mind body, enabling us to do our tasks with mindfulness; the higher intellect, providing us with clarity; and finally, the universal body, giving us limitless bliss.(17) Yoga affects every cell of the human body. It brings about better neuro-effector communication, improves strength and increases resistance against stress. It enhances optimum functioning of all organ-systems, and brings about tranquillity, balance and a positive attitude that creates a purposeful and healthier life. The major benefits of yoga may occur due to its lifestyle components (healthy diet, activity, relaxation and positive attitude) as well as the psychosomatic harmonizing effects of pranayama and yogic relaxation.(18)

Stress is known to adversely affect the neuroendocrine axis and as yoga reduces stress, it may help in reducing severity and symptoms of pruritus (physical factors) and perceived stress of patients with psoriasis.

Bartholomew et al suggested the possibility that meditation can be used as a tool to improve both psoriasis severity and patient quality of life in the short term.(19)

Satyapriya et al concluded that integrated yoga practice reduces perceived stress and improves adaptive autonomic response to stress. (20)

Smith et al concluded yoga appears to provide a comparable improvement in stress, anxiety and health status compared to that of relaxation. (21) Tooley et al reported higher plasma melatonin levels in experienced meditators following meditation. (22)

It is to be noted that regular practice of yoga and meditation alters levels of various neurotransmitters in the brain such as dopamine and GABA. (23,24) Streeter et al recently proposed a theory to explain the benefits of yoga practices in diverse, frequently comorbid medical conditions based on the concept that yoga practices reduce the allostatic load in stress response systems such that optimal homeostasis is restored. (25)

Yoga affects every cell of the human body. It brings about better neuro-effector communication, improves strength and increases resistance against stress. It enhances the optimum functioning of all organ systems and brings about tranquillity, balance and a positive attitude that creates a purposeful and healthier life. The major benefits of yoga may occur due to its lifestyle components (healthy diet, activity, relaxation and positive attitude) as well as the psychosomatic harmonizing effects of pranayama and yogic relaxation. (26)

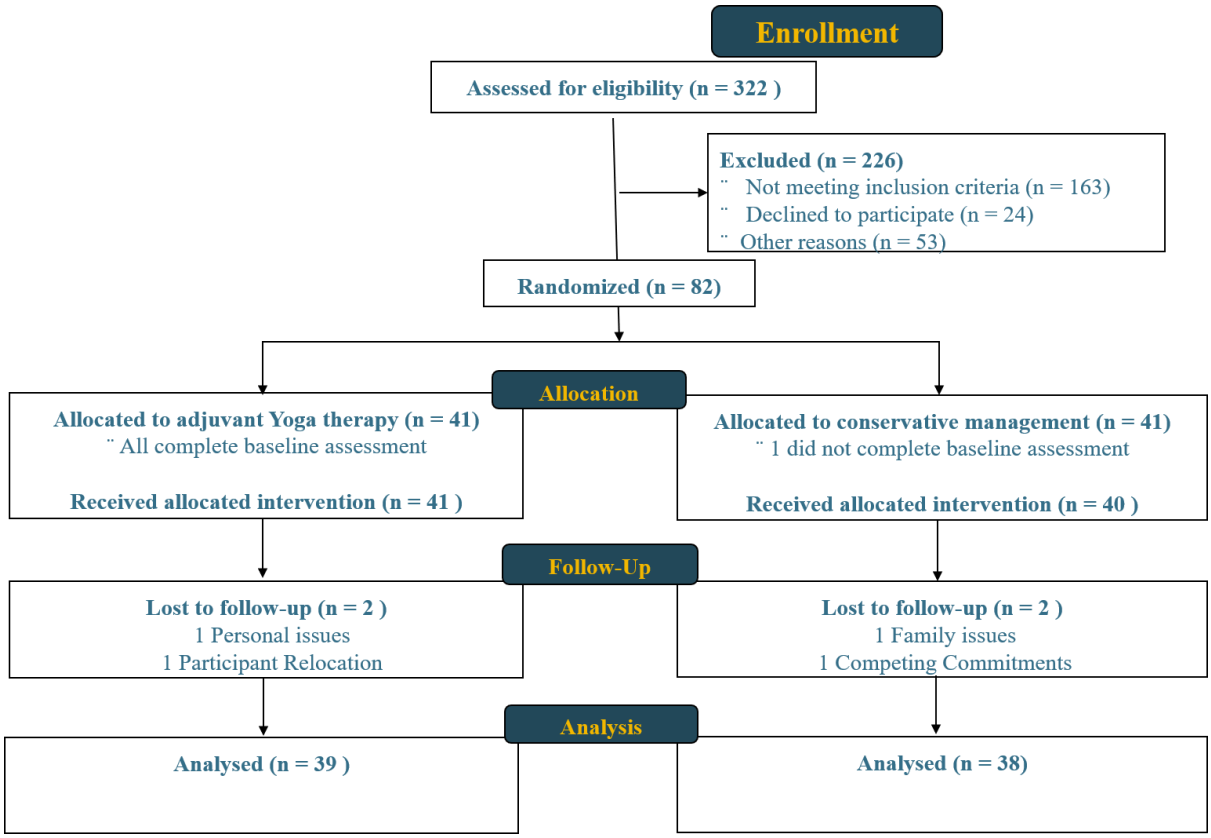
A recent review by Basavaraj et al concluded that stress is one of the important trigger factors in the onset or exacerbation of psoriasis, treatment of stress is prognostically beneficial when patients understand the stress flare phenomenon and gain insight into the nature of any emotional trauma they have suppressed. (27)

Al'abadie et al studied retrospectively in skin patients results support the notion that stress is more likely to be associated with the onset of psoriasis than other conditions. (28) Alipour et al concluded that mindfulness-based practices can be used as a complementary treatment for improving symptoms of pruritus and perceived stress of the patients. (29)

However, the effect of yoga therapy in modifying stress in patients with psoriasis has not been reported so far. To the best of our knowledge, the present study may be the first of its kind to be reported in the literature.

5. Methodology:

5.1 Consort chart:


Enrollment
Assessed for eligibility (n = 322)
Excluded (n = 226)
¨ Not meeting inclusion criteria (n = 163)
¨ Declined to participate (n = 24)
¨ Other reasons (n = 53)
Randomized (n = 82)
Allocation
Allocated to adjuvant Yoga therapy (n = 41)
¨ All complete baseline assessment
Received allocated intervention (n = 41)
Allocated to conservative management (n = 41)
¨ 1 did not complete baseline assessment
Received allocated intervention (n = 40)
Follow-Up
Lost to follow-up (n = 2)
1 Personal issues
1 Participant Relocation
Lost to follow-up (n = 2)
1 Family issues
1 Competing Commitments
Analysis
Analysed (n = 39)
Analysed (n = 38)

5.2 Study Design

This study is a parallel-group, single-centre, open-label randomised controlled trial.

Prior permission was obtained from the Institutional Human Ethics Committee (IHEC) for the study **[Project No: PhD. Dissertation/2018/06/01]** and Registered with the Clinical Trials Registry of India, **Reg.No: CTRI/2018/08/ 015558.**

5.3 Place of Study

The study was conducted at the School of Yoga Therapy (SYT), Institute of Salutogenesis and Complementary Medicine (ISCM) & Mahatma Gandhi Medical

College & Research Institute (MGMCRI), Sri Balaji Vidyapeeth (SBV) Deemed-to-be University, Puducherry.

5.4 Patient selection

5.4.1 Study Population

All psoriasis patients attending Dermatology OPD, MGMCRI.

5.4.2 Inclusion Criteria

- Patients with mild to moderate psoriasis on conservative management.
- Able to perform the techniques in the protocol.
- Age limit: 18 years to 65 years
- Willing to participate in yoga therapy

5.4.3 Exclusion Criteria

- Patients having salivary gland tumour.
- Patients having hormone replacement therapies, contraceptives, oral and injectable steroid.
- Medical condition affecting Hypothalamic–Pituitary–Adrenal (HPA) axis (Cushing's and Addison's syndrome)
- Already participating in yoga on regular basis.

5.4.4 Study Subjects

Our study involves patients with psoriasis fulfilling inclusion criteria.

5.4.5 Sample Size

Sample size is 34 for each group arrived by using sample size calculator. Therefore minimum required sample size would be 68. Adding a dropout rate at 20%, 82 sample size is required to fulfil the minimum required sample size.

$$n_1 = \frac{2\sigma^2 \left[Z_{1-\alpha/2} + Z_{1-\beta} \right]^2}{(\mu_1 - \mu_2)^2}$$

$Z_{1-\alpha/2}$ = 1.96 at 95% of confidence with α = 0.05

$Z_{1-\beta}$ = 0.84 to 80% of power with β = 0.20

μ_1= 23.2 σ=8.7551 from previous study (32)

μ_2= 17.2 [assumed to reduce 6 units after the intervention]

$n_1=2(8.7551)[1.96 + 0.84]^2 / (23.2 – 17.2)^2$

n1= 34

Considering 20% of dropout n=41 in each group

The Total sample size is 82.

5.4.6 Sampling Procedure

Purposive Sampling was used for the study.

5.5 Patient Allocation/Randomisation

Patients (n=82) were block randomised into two groups, Conservative Management (CM) group & Adjuvant Yoga Therapy (AYT) group using random allocation software generated list with a block size of 4 and in a 1:1 ratio. CM group received the conservative medical care while AYT group received Yoga therapy along with conservative medical care for a period of three months.

5.6 Outcome Measures/ Tools Used

- Anthropometry: Weight, BMI.
- Physiological parameter: BP, HR & derived cardiovascular indexes
- Psychological parameter: Perceived Stress Scale (PSS), Dermatology Life Quality Index (DLQI)
- Biochemical parameters: Salivary Cortisol
- Clinical Parameter: Psoriasis Area and Severity Index (PASI) scale.

5.6.1 Anthropometry Parameter (Weight, Height, BMI)

5.6.1.1 Measuring Weight

- Ask the participant to stand on the centre of the scale with both feet evenly spaced apart and weight distributed evenly.
- Instruct the participant to stand still and upright, looking straight ahead with their arms at their sides.
- Wait for the weight to stabilize on the digital display. The scale may beep or indicate when the measurement is complete.

- Read the weight to the nearest 0.1 kg or according to the scale's precision.
- Immediately record the weight on the data recording sheet, noting the date and time of the measurement.

5.6.1.2 Measuring Height

- Ask the participant to stand straight with their back against the stadiometer, feet together, and heels touching the base.
- Ensure the participant's head, shoulders, buttocks, and heels are touching the stadiometer, with the participant looking straight ahead.
- Lower the stadiometer's headpiece until it rests firmly on top of the participant's head.
- Read the height to the nearest 0.1 cm or according to the stadiometer's precision.
- Immediately record the height on the data recording sheet.

5.6.1.3 Calculating BMI

- **Convert Height to Meters**:
  - If height is measured in centimeters, divide by 100 to convert to meters (e.g., 170 cm = 1.70 m).
- **Calculate BMI**:
  - Use the formula: $\text{BMI}=\text{Weight (kg)}/\text{Height (m)}^2$
- **Recording and Interpretation**:
  - Record the BMI on the data recording sheet.
  - Categorize the BMI according to the WHO BMI categories:
    - **Underweight**: BMI < 18.5
    - **Normal weight**: BMI 18.5 – 24.9
    - **Overweight**: BMI 25 – 29.9
    - **Obesity**: BMI ≥ 30

5.6.2 Blood pressure

A non-invasive BP apparatus was used to record heart rate (HR), systolic pressure (SP), and diastolic pressure (DP) readings. To ensure objectivity, all recordings were performed using non-invasive automatic BP monitor (Omron

HEM 7203, Kyoto, Japan) that uses an oscillometric method with an instrumental accuracy of ± 5% for HR and ± 3 mm Hg for BP. The recordings were taken after 5 min of quiet comfortable sitting. Pulse pressure (PP), mean pressure (MP), rate-pressure product (RPP) and double product (DoP) indices were derived from the recorded parameters.

5.6.3 The Perceived Stress Scale (PSS)

PSS developed by Sheldon Cohen, measures the degree to which situations in one's life are appraised as stressful. Items were designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives. The PSS was designed for use in community samples with at least a junior high school education. The items are easy to understand, and the response alternatives are simple to grasp.

Scoring: The scoring is done as: "0" for "never", "1" for "almost never", "2" for "sometimes", "3" for fairly often, "4" for "very often". For the four positively stated items (items 4, 5, 7, & 8), PSS scores are obtained by reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) and then summing across all scale items.

5.6.4 Dermatology Life Quality Index (DLQI)

The Dermatology Life Quality Index questionnaire is designed for use in adults, i.e. patients over the age of 16. It is self-explanatory and can be handed to the patient who is asked to fill it in without the need for a detailed explanation.

Scoring: Each of the ten items is scored from 0 to 3. "0" for "not at all", "1" for "A little", "2" for "A lot", "3" for "very much", providing a 0 to 30 severity score.

Interpretation of DLQI Scores:

- 0 -1: No effect at all on patient's life
- 2 – 5: Small effect on patient's life
- 6 – 10: Moderate effect on patient's life
- 11 – 20: Very large effect on patients' life
- 21 – 30: Extremely large effect on patient's life

5.6.5 Salivary cortisol

The salivary cortisol passive drool method is a non-invasive technique for collecting saliva to measure cortisol levels. Cortisol, often referred to as the "stress hormone," is commonly assessed in research and clinical settings to evaluate stress response, circadian rhythms, and adrenal function**.**

Ensure the participant is calm and has rested for a few minutes before starting the collection. The participant has to lean slightly forward, allowing saliva to naturally pool in the mouth. Ask the participant to let saliva accumulate in their mouth without stimulation (no chewing or sucking). Once they feel they have enough saliva (usually around 1-2 mL), they should drool directly into the collection tube. After that Immediately label the collection tube with the participant's ID, date, and time of collection.

In the lab, the saliva samples will be thawed, centrifuged to remove particulate matter, and store the sample to a -20°C freezer as soon as possible to preserve the integrity of cortisol and then analyzed for cortisol levels using an assay, such as enzyme-linked immunosorbent assay (ELISA)

5.6.6 Psoriasis Area and Severity Index (PASI) Scale

The Psoriasis Area and Severity Index (PASI) is a tool used to measure the severity and extent of psoriasis. It combines the assessment of the severity of lesions and the area affected into a single score, ranging from 0 (no disease) to 72 (maximum disease severity). The PASI score helps dermatologists evaluate the effectiveness of treatments and the progression of the disease.

Interpretation of PASI Scores

- Mild Psoriasis: PASI score < 10
- Moderate Psoriasis: PASI score 10-20
- Severe Psoriasis: PASI score > 20

5.7 Yoga Therapy Protocol

Based on traditional references and previous research studies the following practices were shortlisted after expert validation (Table 1).

Table 1: Yoga therapy protocol

S.No.	Yogic Techniques	Rounds	Duration (min)
1.	Jathis / Breath BodyCo-ordination (Head, Shoulder, Hip & Knee Movements)	3 times each	5
2.	Tala Kriya and Asana	3 times	2
3.	Trikonasana	3 times	2
4.	Meruasana /NasargaMukhaBhastrika	3 times	2
5.	Chatuspadasana/Vyagraha Pranayama	6 rounds	3
6.	Pavanamukta Series (As eka and dwipada kriya and asana)	3 times	3
7.	Sethu kriya and Asana	3 times	3
8.	NadishuddhiPranayama	9 rounds	5
9.	Kavi (Sadanta) Pranayama	9 rounds	3
10.	Bhramari Pranayama	9 rounds	3
11.	Kaya kriya: dynamic body relaxation with movements of lower, upper limbs and head and neck with breathing	3 rounds of each set	6
12.	Spandha Nishpandha Kriya: self-directed complete tensing of whole body followed by its instant relaxation	3 times	3
13.	Shavasana with Pranava pranayama: Breathing in and then breathing out with the sounds of aaa... uuu… and mmm…	3 rounds of each set	10

5.8 Procedure/Conduct of the Study

1) 82 patients of psoriasis on conservative management were recruited after obtaining informed consent.
2) Randomization of subjects (using random allocation software generated list with a block size of 4 and in a 1:1 ratio) was done into

- AYT Group of 41 subjects (yoga therapy for 3 months with conservative management) and
- CM Group of 41 subjects (controls receiving only conservative management).

3) Pre study evaluation of Anthropometry (weight, BMI), Physiological parameter (BP, HR), Psychological parameter (PSS, DLQI), Biochemical parameter (Salivary Cortisol), Clinical Parameter (Psoriasis Area and Severity Index (PASI) scale).
4) While the subjects in conservative management (CM) group received conservative medical care, subjects in the adjuvant yoga therapy (AYT) group received 10 supervised sessions within the period of 3 months.
5) Yoga Therapy as per the SYT protocol was given to subjects in the experimental (AYT) group.
6) Participants were motivated to practice at home and maintain a diary that was used to evaluate compliance of the study.
7) Yoga pamphlets were given to subjects in the AYT group for home practice and the subjects were followed up regularly once a week for recording their compliance with yoga.
8) Post-test analyses of all parameters was done again at end of 3-month study period to assess effects of yoga therapy.

5.9 Statistical Analysis

- All data passed the Normality test.
- Student's paired t-test was used for intra-group comparisons.
- Student's unpaired t-test was used for inter-group comparisons.
- Chi-square was used to express significant association between categorical variables.
- Delta percentage (Δ%) was calculated by the formula (post-pre/pre) X 100 for all the outcome variables to evaluate the pre-post change in the scores.
- ANOVA tests have been used for subgroup analysis
- JASP (version 16.4) was used for all statistical analyses.

6. Result & Discussion

6.1 Socio-demographic data

The socio-demographic characteristics of the subjects which were collected include Gender, Education, Children, Income, Marital Status, and Number of Siblings (**Table 1**). These data are considered intervening variables and therefore provide important context for interpreting the study's findings, as they may interact with the interpretation of intervention outcomes. It also ensures if randomisation was successful. All socio-demographic variables were comparable at the baseline as determined by respective chi-square (χ^2) values.

Table 1: Demographic variables of the conservative management group & Adjuvant yoga therapy group.

		CM		**AYT**		**χ^2**	**P value**
		N	Percentage	N	Percentage		
Gender	Male	24	63.16	24	61.54	0.021	0.883
	Female	14	36.84	15	38.46		
Education	No Formal	5	13.158	5	12.821	0.643	0.887
	Primary	8	21.053	11	28.205		
	Secondary	12	31.579	10	25.641		
	Degree	13	34.211	13	33.333		
Children	No Children	7	18.421	10	25.641	3.024	0.554
	1	12	31.579	8	20.513		
	2	13	34.211	12	30.769		
	3	4	10.526	8	20.513		
	More than 3	2	5.263	1	2.564		
Occupation	Daily Wager	4	10	6	15	6.988	0.137
	Private Sector	14	35	21	52.5		
	Public Sector	0	0	1	2.5		
	Self - Emp	11	27.5	6	15		
	Unemployment	11	27.5	6	15		
Income	No Income	6	15	7	17.5	1.298	0.862
	< 5000	13	32.5	10	25		
	< 15000	9	22.5	10	25		
	< 30000	10	25	12	30		
	> 30000				2.5		

Marital Status	Married	32	80	33	82.5	0.385	0.825
	Unmarried	6	15	6	15		
	Divorced or Separated	2	5	1	2.5		

Siblings	0	4	10	3	7.5	1.687	0.64
	1	14	35	10	25		
	2	15	37.5	17	42.5		
	More than 2	7	17.5	10	25		

6.2 Baseline Comparison

Pre-test comparison between conservative management (CM) & adjuvant yoga therapy (AYT) groups. The primary purpose of pre-test comparison is to ensure that the groups are equivalent at the start of the study (**Table 2 to Table 6**).

Table 2: Baseline comparison of anthropometric parameters of conservative management group (n=38) and adjuvant yoga therapy group (n=39).

		Mean	**SD**	**SE**	**Mean Diff.**	**T-Test**	**P Value**
Weight (Kg)	CM	69.579	12.082	1.96	2.823	0.989	0.326
	AYT	66.756	12.933	2.071			
BMI (Kg/m^2)	CM	27.692	5.326	0.864	1.988	1.733	0.087
	AYT	25.704	4.729	0.757			

Table 3: Baseline comparison of physiological parameters (Cardiovascular indexes) of conservative management group (n=38) and adjuvant yoga therapy group (n=39).

		Mean	**SD**	**SE**	**Mean Diff.**	**T-Test**	**P Value**
SP	CM	122.21	12.37	2.01	2.954	1.015	0.313
	AYT	119.26	13.14	2.10			
DP	CM	76.05	8.51	1.38	-0.922	-0.403	0.688
	AYT	76.97	11.33	1.81			
HR	CM	83.50	11.36	1.84	1.731	0.681	0.498
	AYT	81.77	10.94	1.75			
PP	CM	46.16	10.43	1.69	3.876	1.483	0.142
	AYT	42.28	12.40	1.99			
MAP	CM	91.44	8.67	1.41	0.37	0.169	0.866
	AYT	91.07	10.44	1.67			
RPP	CM	101.91	16.10	2.61	4.292	1.115	0.268
	AYT	97.62	17.62	2.82			
DoP	CM	7628.79	1204.37	195.37	172.866	0.588	0.559
	AYT	7455.92	1369.54	219.30			

Values are in Mean. SP - Systolic Pressure (mmHg); DP – Diastolic Pressure (mmHg); HR – Heart Rate (beats/min); PP – Pulse Pressure (mmHg); MAP – Mean Arterial Pressure (mmHg); RPP – Rate Pressure Product (mmHg/min); DoP – Double product (mmHg)

Table 4: Baseline comparison of psychological parameters of the conservative management group (n=38) and adjuvant yoga therapy group (n=39).

		Mean	**SD**	**SE**	**Mean Diff.**	**T-Test**	**P Value**
PSS	CM	26.97	4.50	0.73	-1.36	-1.432	0.156
	AYT	28.33	3.81	0.61			
DLQI	CM	15.95	5.32	0.86	-0.258	-0.23	0.819
	AYT	16.21	4.50	0.72			

Values are in Mean. PSS – Perceived Stress Scale; DLQI – Dermatology Life Quality Index

Table 5: Baseline comparison of bio-chemical parameter of the conservative management group (n=38) and adjuvant yoga therapy group (n=39).

		Mean	**SD**	**SE**	**Mean Diff.**	**T-Test**	**P Value**
Salivary Cortisol (nmol/L)	CM	4.36	1.01	0.16	-0.011	-0.054	0.957
	AYT	4.37	0.79	0.13			

Values are given as Mean.

Table 6: Baseline comparison of clinical parameter of the conservative management group (n=38) and adjuvant yoga therapy group (n=39).

		Mean	**SD**	**SE**	**Mean Diff.**	**T-Test**	**P Value**
PASI	CM	17.17	4.87	0.79	-0.27	-0.234	0.816
	AYT	17.44	5.24	0.84			

Values are in Mean, PASI - Psoriasis Area and Severity Index.

The pre-test comparisons across various parameters show no statistically significant differences between the CM and AYT groups. This indicates that the groups are comparable at baseline, supporting the internal validity of the study.

6.3 Comparison of inter & intra group analysis of conservative management (n = 38) & adjuvant yoga therapy (n = 39).

Comparison of inter-group and intra-group analysis for the conservative management group & adjuvant yoga therapy is vital in experimental research to ensure that the observed effects are truly due to the intervention.

The comparison of CM and AYT on anthropometry parameters, physiological parameters, psychological parameters, biochemical parameter and clinical parameter of the psoriasis population is given in Table 7 to Table 11. The tables provide a clear representation of the change in both groups and also the comparison between both groups.

Table 7: Comparison of conservative management (CM) and adjuvant yoga therapy (AYT) group and post-analysis of inter-group comparison on anthropometry parameters.

Anthropometry parameters	**CM (n=38)**		**AYT (n=39)**		**p-value**
	B	**A**	**B**	**A**	**A-A**
Weight (Kg)	69.58 ±12.08	69.24 ± 11.67	66.76 ± 12.93	66.10 ± 12.18$^{\#\#}$	0.253
BMI (Kg/m^2)	27.69 ± 5.33	27.57 ± 5.21 #	25.70 ± 4.73	25.48 ± 4.49 $^{\#\#}$	0.063

Values are given as Mean ± SD. Students paired t-test is used for intra-group comparison where # p<0.05, ##p<0.01, ###p< 0.001; students unpaired t-test is used for inter-group comparison. Actual p values are given for inter-group comparisons.

- In Intra-group comparison, the AYT & CM groups experienced mild weight loss and a mild decrease in BMI, but the AYT group showed a significant reduction. Both CM and AYT do not impact body weight & BMI greatly.
- In Inter-group comparison, The AYT group had a slightly lower mean weight & BMI compared to the CM group. However, this was not significant.

Table 8: Comparison of conservative management (CM) and adjuvant yoga therapy (AYT) group and post-analysis of inter-group comparison on physiological parameters (Cardiovascular indexes).

Physiology parameters	**CM (n=38)**		**AYT (n=39)**		**p-value**
	B	**A**	**B**	**A**	**A-A**
SP (mmHg)	122.21 ± 12.37	121.03 ± 13.32	119.26 ± 13.14	116.00 ± 9.15 $^{\#}$	**0.057**
DP (mmHg)	76.05 ± 8.51	75.08 ± 10.40	76.97 ± 11.33	75.39 ± 7.81	0.063
HR (beats/min)	83.50 ± 11.36	82.03 ± 9.20	81.77 ± 10.94	77.18 ± 10.96 $^{\#\#\#}$	0.884
PP (mmHg)	46.16 ± 10.43	45.95 ± 11.72	42.28 ± 12.40	40.62 ± 10.26	**0.039**
MAP (mmHg)	91.44 ± 8.67	90.40 ± 10.03	91.07 ± 10.44	88.92 ± 6.72	**0.037**

RPP (mmHg/min)	101.91 ± 16.10	99.11 ± 13.97 #	97.62 ± 17.62	89.72 ± 15.61 ###	0.451
DoP (mmHg/min)	7628.79 ± 1204.37	7395.49 ± 1012.94 #	7455.92 ± 1369.54	6876.33 ± 1192.05 ###	**0.007**

Values are given as Mean ± SD. Students paired t-test is used for intra-group comparison where # p<0.05, ##p<0.01, ###p< 0.001; students unpaired t-test is used for inter-group comparison. Actual p values are given for inter-group comparisons.

- In intra-group comparison, The AYT group showed a greater reduction in systolic blood pressure, implying improved cardiovascular health from the intervention. The AYT group had a significant reduction in heart rate, indicating improved cardiovascular efficiency and stress reduction. The AYT group had a more marked reduction in MAP, reflecting improved overall blood pressure control and reduced cardiovascular risk. But There were no significant changes within the groups. The AYT group significant reduction in RPP indicates reduced myocardial oxygen demand and improved cardiac function. A lower DoP in the AYT group suggests better cardiac efficiency and reduced heart workload.
- In Inter-group comparison, The AYT group's significantly lower pulse pressure suggests better arterial health. Lower pulse pressure can indicate reduced arterial stiffness and lower cardiovascular risk. Significant lower RPP in the AYT group suggests reduced myocardial oxygen demand, indicating improved cardiac efficiency. Similar to RPP, a significant lower DoP in the AYT group reflects better cardiac function and lower workload on the heart.

Table 9: Comparison of conservative management (CM) and adjuvant yoga therapy (AYT) group and post-analysis of inter-group comparison on psychological parameters.

Psychological Parameter	**CM (n=38)**		**AYT (n=39)**		**p-value**
	B	**A**	**B**	**A**	**A-A**
PSS	26.97 ± 4.49	23.26 ± 4.41###	28.33 ± 3.81	17.67 ± 2.72###	**< 0.001**
DLQI	15.95 ± 5.31	8.37 ± 3.01###	16.21 ± 4.49	7.13 ± 1.88###	**0.033**

Values are given as Mean ± SD. Students paired t-test is used for intra-group comparison where # p<0.05, ##p<0.01, ###p< 0.001; students unpaired t-test is used for inter-group comparison. Actual p values are given for inter-group comparisons.
PSS – Perceived Stress Scale; DLQI – Dermatology Life Quality Index

- In Intra-group comparison, Both the CM & AYT groups have significant reductions in perceived stress scale score. The AYT group experienced a significantly greater reduction in perceived stress, highlighting the effectiveness of

the intervention in managing stress. In the dermatology life quality index score, Both groups showed highly significant improvement.

- In Inter-group comparison, The AYT group reported significantly lower perceived stress levels, indicating the effectiveness of the yoga intervention in reducing psychological stress. The AYT group reported a better quality of life related to dermatological conditions, possibly due to reduced stress improving skin conditions. AYT has a promotive impact on psychological health that manifest in salutogenic wellness.

Table 10: Comparison of conservative management (CM) and adjuvant yoga therapy (AYT) group and post-analysis of inter-group comparison on biochemical parameter.

Biochemical Parameter	CM (n=38)		AYT (n=39)		p-value
	B	A	B	A	A-A
Salivary Cortisol (nmol/L)	4.36 ± 1.01	5.09 ± 1.33##	4.37 ± 0.79	4.25 ± 1.32	**0.007**

Values are given as Mean ± SD. Students paired t-test is used for intra-group comparison where # p<0.05, ##p<0.01, ###p< 0.001; students unpaired t-test is used for inter-group comparison. Actual p values are given for inter-group comparisons.

- In intra-group comparison, the CM group had an increase in cortisol levels suggesting that participants may have experienced stress during the period of study. This is plausible because it was the immediate post-COVID time. In the AYT group slight decrease in cortisol levels indicates that the yoga intervention may have helped reduce stress levels.
- In Inter-group comparison, Lower salivary cortisol levels in the AYT group indicate reduced physiological stress. As suggested earlier yoga may be an effective tool to mitigate the post-pandemic stress-induced rise in the CM group. This may be due to reduced activity of the hypothalamic-pituitary-adrenal (HPA) axis.

Table 11: Comparison of conservative management (CM) and adjuvant yoga therapy (AYT) group and post-analysis of inter-group comparison on clinical parameter.

Clinical Parameter	CM (n=38)		AYT (n=39)		p-value
	B	A	B	A	A-A
PASI	17.77 ± 4.87	7.64 ± 3.52###	17.37 ± 5.25	6.03 ± 1.98###	**0.014**

Values are given as Mean ± SD. Students paired t-test is used for intra-group comparison where # p<0.05, ##p<0.01, ###p< 0.001; students unpaired t-test is used for inter-group comparison. Actual p values are given for inter-group comparisons.
PASI - Psoriasis Area and Severity Index

- In intra-group comparison, Both groups showed improvement, but the AYT group had a more substantial reduction in psoriasis severity, suggesting the intervention's positive impact on skin conditions.
- In inter-group comparison, The AYT group showed a greater reduction in psoriasis severity, suggesting that stress reduction through yoga has beneficial effects on inflammatory skin conditions.

Table 12: Comparison of delta% of CM and AYT groups

Anthropometry parameters		Mean	SD	SE	W	P value
Weight	CM	0.406	1.016	0.165	636	0.201
	AYT	0.825	1.545	0.247		
BMI	CM	0.386	1.041	0.169	653.5	0.329
	AYT	0.745	1.556	0.249		

Physiology parameters		Mean	SD	SE	W	P value
SP	**CM**	0.976	4.637	0.752	661.5	0.421
	AYT	2.11	8.128	1.302		
DP	**CM**	1.197	8.86	1.437	720.5	0.838
	AYT	0.076	18.176	2.91		
HR	**CM**	1.23	7.264	1.178	539.5	**0.041**
	AYT	5.258	9.514	1.523		
PP	**CM**	-0.516	19.765	3.206	720.5	0.839
	AYT	-3.514	44.161	7.071		
MAP	**CM**	1.171	5.198	0.843	674.5	0.501
	AYT	1.352	11.747	1.881		
RPP	**CM**	2.264	7.613	1.235	492	**0.011**
	AYT	7.476	10.28	1.646		
DoP	**CM**	2.42	8.292	1.345	522	**0.025**
	AYT	6.448	15.478	2.478		

Psychological Parameter		Mean	SD	SE	W	P value
PSS	**CM**	10.102	26.936	4.37	181.5	< .001
	AYT	37.322	4.677	0.749		
DLQI	**CM**	45.439	22.36	3.627	594	0.135
	AYT	50.952	24.64	3.945		
Biochemical Parameter		**Mean**	**SD**	**SE**	**W**	**P value**
Salivary Cortisol	**CM**	-24.281	49.164	7.975	458	**0.004**
	AYT	0.995	35.832	5.738		

Clinical Parameter		Mean	SD	SE	W	P value
PASI	**CM**	-55.568	12.918	2.096	996.5	**0.009**
	AYT	-63.596	10.734	1.719		

Overall Interpretation of Delta Percentages:

- Weight and BMI: Minimal changes, indicating these parameters are relatively stable and not significantly impacted by the interventions.
- Physiological Parameters: Notable changes in heart rate, rate pressure product, and double product, particularly in the AYT group, suggesting significant cardiovascular effects.
- Psychological Parameters: Significant reduction in perceived stress in the AYT group, potentially due to increased mindfulness and awareness of stress. Dermatology life quality is similarly affected in both groups.
- Bio-Chemical Parameter: Significant increase in salivary cortisol in the CM group, indicating reduced biochemical stress.
- Clinical Parameter: The significant reduction in PASI scores indicates that the treatment or intervention led to a meaningful improvement in the clinical condition of the participants.

Table 13: Correlation of variables:

Variable		PSS	DLQI	Salivary Cortisol	PASI
SP	Pearson's r	0.08	0.022	**0.268**	-0.011
	p-value	0.489	0.85	**0.019****	0.921
MAP	Pearson's r	0.123	0.04	**0.252**	0.031
	p-value	0.288	0.729	**0.027****	0.787
RPP	Pearson's r	-0.067	-0.003	**0.26**	-0.003
	p-value	0.563	0.98	**0.022****	0.982
DoP	Pearson's r	-0.039	0.009	**0.248**	0.028
	p-value	0.739	0.936	**0.03****	0.809

Variable		PSS	DLQI	Salivary Cortisol	PASI
PSS	Pearson's r	—	**0.853**	-0.09	**0.676**
	p-value	—	**< .001**	0.437	**< .001**
DLQI	Pearson's r	**0.853**	—	-0.067	**0.808**
	p-value	**< .001**	—	0.561	**< .001**
Salivary Cortisol	Pearson's r	-0.09	-0.067	—	-0.002
	p-value	0.437	0.561	—	0.984
PASI	Pearson's r	**0.676**	**0.808**	-0.002	—
	p-value	**< .001**	**< .001**	0.984	—

- PSS and DLQI: There is a strong positive correlation between PSS and DLQI, indicating that higher perceived stress is associated with poorer quality of life related to dermatology conditions. Both PSS and DLQI are significantly positively correlated with PASI, suggesting that higher stress and lower quality of life are associated with more severe psoriasis.
- Salivary cortisol do not correlate with PSS, DLQI and PASI.
- Physiological Parameters (SP, MAP, RPP, and DoP) all show significant correlations with salivary cortisol but not with PASI, suggesting these physiological measures are more reflective of stress responses rather than direct indicators of psoriasis severity.
- Overall, the significant correlations between stress, quality of life, and psoriasis severity highlight the importance of psychological factors in the management of psoriasis.
- Interventions aimed at reducing stress and improving quality of life could potentially lead to better clinical outcomes for individuals with psoriasis.

Regression:

Linear Regression						
Model Summary - PASI						
Model	**R**	**R^2**	**Adjusted R^2**	**RMSE**		
H_0	0	0	0	9.159		
H_1	0.962	0.925	0.918	2.625		
ANOVA						
Model		**Sum of Squares**	**df**	**Mean Square**	**F**	**p**
H_1	**Regression**	5900.05	7	842.864	122.316	< .001
	Residual	475.47	69	6.891		
	Total	6375.52	76			
Note. The intercept model is omitted, as no meaningful information can be shown.						
Coefficients						
Model		**Unstandardized**	**Standard Error**	**Standardized[a]**	**t**	**p**
H_0	**(Intercept)**	21.2	1.044		20.311	< .001
H_1	**(Intercept)**	18.625	21.585		0.863	0.391
	pss0	0.937	0.154	0.429	6.09	< .001
	dlqi0	1.043	0.127	0.557	8.202	< .001
	rpp0	0.091	0.048	0.169	1.898	0.062
	hr0	-0.547	0.254	-0.664	-2.154	0.035
	map0	-0.465	0.228	-0.484	-2.034	0.046
	dp0	0.005	0.003	0.706	1.772	0.081
	gender (2)	1.098	0.674		1.628	0.108

The linear regression analysis of Psoriasis Area Severity Index (PASI) provided the following insights:

The high R^2 value (0.925) indicates that 92.5% of the variance in PASI can be explained by the model, suggesting a strong predictive power.

The significant F-statistic ($p < 0.001$) confirms that the regression model is statistically significant, meaning it effectively predicts PASI based on the included variables.The linear regression analysis indicates that perceived stress (PSS), dermatology life quality (DLQI), heart rate (HR), and mean arterial pressure (MAP) are significant predictors of the Psoriasis Area Severity Index (PASI). Specifically: **PSS and DLQI** have a positive and significant relationship with PASI, meaning higher stress levels and poorer quality of life are associated with higher PASI scores. **Heart Rate (HR) and Mean Arterial Pressure (MAP)** show a negative and significant relationship with PASI, suggesting lower HR and MAP are associated with lower PASI scores. The model explains a substantial portion of the variability in PASI, making it a robust tool for understanding the impact of these variables on psoriasis severity.

7. Summary and Conclusion:

The intervention, likely yoga therapy, has significantly positively affected the AYT group across various health metrics. Key findings include:

- Weight and BMI: As the changes were mild, clinical improvements in our participants were not mediated by weight loss alone.
- Cardiovascular Health: Significant improvements in blood pressure, heart rate, pulse pressure, and mean arterial pressure in the AYT group, reflected better cardiovascular health. This was correlated with Salivary cortisol changes, hence highlighting role of stress in cardiovascular health.
- Perceived Stress: A notable reduction in perceived stress levels in the AYT group, highlighting the intervention's effectiveness in stress management.
- Quality of Life: Significant improvements in dermatology-related quality of life and reductions in psoriasis severity in the study group, possibly due to reduced stress levels.
- Biochemical marker: Better regulation of salivary cortisol in the study group, indicating that yoga reduces the negative impact of stress.
- Overall, the data suggests that the yoga therapy-based stress reduction program was effective in improving both physiological and psychological health outcomes more significantly in the study group compared to the control group.

- This supports the integration of yoga therapy in clinical protocol in dermatology as a beneficial intervention for stress reduction and overall well-being.

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Original Research Article

Effect of yoga therapy on cardiovascular parameters in patients with psoriasis: A randomized control trial — pilot study

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ABSTRACT

Aim and Objective: This study was done at the Centre for Yoga Therapy, Education and Research (CYTER) of Sri Balaji Vidyapeeth (SBV) to determine cardiovascular (CV) parameters in patients with psoriasis.

Materials & Methods: Data of 20 patients (12 female, 8 male) with a mean age of 44.40 ± 15.2 y who were referred by Dept. of Dermatology and attended yoga therapy sessions at CYTER was used for analysis. Supervised yoga training was given to the participants who were randomized into the yoga group. Heart rate (HR), systolic and diastolic pressure (SP and DP) was recorded using non-invasive blood pressure (NIBP) apparatus before and after the study period of 12 weeks. CV indices such as Pulse pressure (PP), mean pressure (MP), rate-pressure product (RPP), and double product (DoP) were derived using appropriate formulae.

Results: The inter-group comparison showed significant change ($p<0.05$) in SP. The derived CV indices such as PP, RPP & DoP also showed significant changes. ($p<0.05$) after 12 weeks of Yoga training. The intragroup comparison in the control group showed a significant increase in SP and DP ($p<0.05$).

Conclusion: There is a healthy reduction in SP and derived CV indices following 12 weeks of yoga training. The magnitude of this reduction depends on the pre-existing medical condition and intensity of the disease in each individual. These changes may be attributed to enhanced harmony of cardiac autonomic function as a result of coordinated breath-body work and mind-body relaxation due to yoga resulting in a significant reduction in the perceived stress.

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1. Introduction

Psychodermatologic disorder is a condition that involves an interaction between the mind and the skin.[1] Psoriasis, which are not directly connected to mind, but it was precipitated or exacerbated by psychological stress. Psoriasis is a genetically determined immune-mediated inflammatory disease mediated by T-helper 1 (Th1)/Th17 T cells. With a prevalence of 0.44–2.8 percent in India, it commonly affects individuals in their third or fourth decade with males being affected two times more common than females.[2] Psoriasis has greater impact on the quality of life of patients and their families leads to great physical, emotional and social burden. Yoga is the unique combination of isometric muscular contractions, stretching exercises, relaxation techniques, and breathing exercises.[3,4] Numerous studies have been done in the past few decades on psycho physiological and biochemical changes occurring following the practice of yoga.[5–7] Various studies show adjuvant Yoga therapy alleviates stress in normal subjects and patients with different conditions.[8]

2. Materials and Methods

This randomized controlled pilot trial of 12 weeks was undertaken as an interdisciplinary collaborative

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Evaluating Cardiovascular Changes After a Single Yoga Session: A Retrospective Study

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Abstract

Aim and objective: This retrospective review of clinical data was done at the School of Yoga Therapy (SYT) (formerly Centre for Yoga Therapy, Education and Research (CYTER)) of Sri Balaji Vidyapeeth (SBV) to determine the cardiovascular (CV) effects of a single yoga session in patients of different medical conditions as well as in normal subjects. Methods: Data of 6026 patients (3962 female, 1880 male, and 184 transgender) who attended yoga therapy sessions at SYT. Heart rate (HR), systolic (SP) and diastolic pressure (DP) had been recorded using non-invasive blood pressure (NIBP) apparatus Participants were undergoing appropriate yoga therapy protocols as per their condition while normal subjects had a general schedule of practice. Results: There were statistically significant reductions ($p<0.001$) in all the studied CV parameters following the yoga session. Conclusion: There is a healthy reduction in HR, BP, and derived CV indices following a single yoga session. A similar study published earlier in 2013 from SYT (formerly CYTER) has been done with a larger population, and the effect of Yoga therapy on different medical conditions is proved yet again.

Keywords: *Yoga therapy; Cardiovascular effects; Psycho-somatic harmony; Single yoga session*

1. Introduction

CV disease is the leading cause of death in most countries according to the Centers for Disease Control and Prevention (CDC)[1] and the top-ranked risk factor for mortality worldwide.[2] Several risk factors such as smoking, a high-fat diet, a sedentary lifestyle, and psychological factors, including stress, depression, and hostility contribute to coronary heart disease.[3] and studies suggest that yoga may significantly improve risk factors for CV disorder like body weight, lipid profile, blood pressure, smoking, psychosocial stress, and type 2 diabetes mellitus.[4] Lifestyle modifications are essential factors in treating, preventing, and rehabilitating CV disorders.[5]

World Health Organization (WHO) warns people on the increase in CV disorders which is the main cause of concern globally. Most CV disorders could be prevented by managing their risk factors. Lifestyle modification lessens the risk of CV disorders and is thus useful for primary prevention as well as better management.

Yoga envisages health in totality and is the integration and harmony between thought, word, and deed and is an integrated system of self-culture that aims at all aspects of human existence promoting physical wellness and mental harmony culminating in positive thinking, happiness, and peace of mind.[6]

Yoga, the mind-body practice that originated in ancient Indian philosophy has been gaining popularity as a therapeutic modality and extensively studied for its beneficial effects on human health and that yoga-based lifestyle might retard and possibly revert the progression of CV disorder. [7,8]

Yoga practices promote various benefits such as the autonomic functions being normalized, stress getting reduced, physiological functions and quality of life get enhanced. [9,10] The pharmacological treatment used in treating CV disorder has partial effectiveness along with various adverse side effect

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